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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,027	08/27/2003	Fred H. Burbank	R0367.00302	6463

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6N

Office Action Summary	Application No. 10/650,027	Applicant(s) BURBANK ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-38, 40-54 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-38, 40-46, 48-54 and 56-62 is/are rejected.
- 7) ☒ Claim(s) 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed December 17, 2004. The Examiner acknowledges the cancellation of claims 1, 39 and 55; the amendments to claims 28, 31-33, 36, 37, 40-43, 45-48 and 53; and the addition of new claims 58-62. Claims 28-38, 40-54 and 56-62 are pending.

Priority

2. The cancellation of the Benefit Claims to prior Application Serial No. 09/159,467; Application Serial No. 09/057,303; and U.S. Provisional Application No. 60/076,973 via the Supplemental Amendment filed September 21, 2004 is acknowledged. In view of the amended domestic priority claim, the effective filing date of the present application is the March 27, 2001 filing date of prior Application Serial No. 09/819,185.

Terminal Disclaimer

3. The terminal disclaimer filed on December 17, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the full statutory terms of U.S. Patent Nos. 6,261,241; 6,689,071; and 6,497,706 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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Claim Objections

4. Claim 44 is objected to because of the following informalities: in line 4, "tissue" apparently should be deleted. Appropriate correction is required.
5. Claim 59 is objected to because of the following informalities: in line 1, "28" apparently should read --58--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 58-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 58 and 62, the claims recite that the "tissue cutting electrode... has a chord length greater than the transverse dimension of the distal end" of the elongate shaft. The disclosure of the present application does not provide support for this limitation. Furthermore, the term "chord length" is only defined in prior application serial nos. 10/179,933 and 09/717, 176, which are not claimed by Applicant as related to the present application.

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Regarding claims 61 and 62, the claims recite that an elongated cutting member is slidably disposed within the inner lumen of the elongate shaft and has a cutting surface that is transversely disposed with respect to the longitudinal axis of the shaft. The disclosure of the present application does not provide support for this limitation. The specification of the present application defines a stylet shaft and a cannula shaft that may be considered to be the claimed elongated shaft of claims 58 and 62. If the stylet shaft is considered to be the claimed elongated shaft, the stylet shaft has an inner lumen in which a conductor is disposed. The disclosure does not recite that any cutter member is disposed within the inner lumen of the stylet shaft.

Alternatively, if the cannula shaft is considered to be the claimed elongated shaft, the cannula shaft includes an inner lumen and a cutting element that has a cutting surface transversely disposed with respect to a longitudinal axis of the cannula shaft. The cutting element is disclosed as being slideable *with* the cannula shaft. At no time in the disclosure of the present application is an elongated cutting member with a cutting surface transversely disposed relative to the longitudinal axis disclosed as being *slidably disposed within* a shaft or an inner lumen of a shaft, as recited in claims 61 and 62.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 28-38, 40, 41 and 48-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 28, the claim recites that the distal end of the elongate stylet has a

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transverse dimension perpendicular to the longitudinal axis of the cannula that is larger than the transverse dimension of the open distal end of the elongate cannula. The specification of the present application is silent with respect to the transverse dimensions of the cannula and the stylet. However, the figures of the present application illustrate two possible ways of interpreting this limitation. Figures 1, 1a, 4, 5, 20 and 21 illustrate that the outer diameter of the cannula is substantially equal to the outer diameter of the distal end of the stylet. In view of these figures, this limitation would be inaccurate. Figures 5 and 14 illustrate that the inner diameter of the cannula is smaller than the outer diameter of the distal end of the stylet. When interpreted in this fashion the claim language is accurate. In view of the foregoing, the claim language is indefinite because it is unclear how the transverse dimension of the distal end of the stylet is larger than the transverse dimension of the open distal end of the cannula.

Regarding claim 48, it is unclear whether the claim is accurate. Specifically it is unclear whether the second tissue cutting element has only one transverse dimension that is larger than the transverse dimension of the first tissue cutting element or a plurality of transverse dimensions as indicated in lines 14-15 of the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 28, 34-36, 42, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al. ('034). Bryan et al. teach a biopsy system including an elongate cannula **24** with an open distal end and an inner lumen; a first tissue cutting element disposed on the open distal end of the cannula and lying in a plane traversing the longitudinal axis of the cannula; an elongate stylet **16** slidably disposed within the inner lumen configured for translation between a withdrawn position and an extended position; and a second tissue cutting element **13** disposed on a distal end of the stylet that has an elongated tissue cutting surface lying in a plane parallel with the longitudinal axis of the stylet. The transverse dimension of the distal end of the stylet is larger than the transverse dimension of the open distal end of the cannula and the first cutting element, such that the distal end of the stylet is configured to receive the first tissue cutting element. The distal end of the stylet can be said to be a conical head having an insulative frustum-shaped base portion terminating in a tissue cutting apex portion spaced away from the shaft by the base portion (see Fig. 3). A driving unit is coupled to the proximal end of the stylet for translating the stylet (see Figs. 1, 2, 10, 11, 16-18, 23 and 28).

12. Claims 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann et al. ('044). Hofmann et al. teach an electrosurgical stylet including a shaft **14** with an inner lumen **21**, a head **18** fixed to the distal end of the shaft; and a tissue ablation/cutting electrode **15** extending over and is secured to the distal end, which is spaced distally from the head, and which appears to have a chord length (defined as the length between points **12** and **13**) that is greater

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than the transverse dimension of the distal end of the shaft. Electrical conductors **23,24** having one end electrically connected to the tissue ablation/cutting electrode and an opposite end connected to a high frequency electrical power source **16**.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 29-32, 38, 40, 41, 43-46, 49-52, 54, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. ('034) in view of Eggers et al. ('964). Bryan et al., as discussed hereinabove, teach all of the limitations of the claims except that the first and second tissue cutting elements are electrosurgical cutting elements. Eggers et al. teach a cannula and stylet biopsy system having a first electrosurgical cutting element disposed on the stylet and a second electrosurgical cutting element disposed on the cannula that cauterize and ablate tissue as a biopsy sample is taken. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the first and second tissue cutting elements of a biopsy system similar to that of Bryan et al. as electrosurgical cutting elements in view of the teachings of Eggers et al. in order to cauterize tissue as a biopsy is taken to minimize bleeding and the risk of infection in the vicinity of the biopsy site.

Allowable Subject Matter

15. Claims 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claims 33, 37 and 53 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

17. Applicant's arguments, see pages 13 and 14 of the Remarks filed September 14, 2004, with respect to the rejection(s) of claim(s) 28-31, 33, 34, 42-45, 47-51 and 53 under 35 U.S.C. 102(e) as being anticipated by Milliman et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bryan et al. ('955) and Eggers et al. ('964). Bryan et al. teaches a biopsy device with a stylet having a distal end with a larger transverse dimension than an open distal end of a cannula disposed thereabout.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bryan et al. ('636) and Kieturakis ('626) teach biopsy apparatus that read on at least independent claims 28, 42 and 48.

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19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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March 1, 2005